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| 09/508,670      | 03/28/2000  | FREDERIC BONTE       | 00060               | 7942             |

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DENNISON, SCHULTZ, DOUGHERTY & MACDONALD  
1727 KING STREET  
SUITE 105  
ALEXANDRIA, VA 22314

EXAMINER

SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/508,670

**Applicant(s)**

BONTE ET AL.

**Examiner**

Shahnam Sharareh

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 70-93 is/are pending in the application.
- 4a) Of the above claim(s) 79-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-78 and 88-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 70-93 are pending. Applicant has made an election of species set forth in Paper No. 12, filed on May 24, 2002. Accordingly, the examination of the pending claims is directed to the same species elected on May 24, 2002. Claims directed to such species encompassing methods of improving cohesion between dermis and epidermis, comprising delivering to skin or hair a person in need thereof, a cosmetically effective amount of ellagic acid, a retinoid, and *pygeum africanum*.

Subsequent to the renumbering of the claims on the last Office Action, claims 70-78, 88-93 are directed to the elected species and are thus under consideration. Accordingly at this point, claims 79-87 are withdrawn from further consideration, because they are directed to the non-elected species.

### ***Response to Arguments***

2. Applicant's arguments filed on October 29, 2004 have been considered and are found partially persuasive. Applicant's arguments with respect to the prior art rejections of record have been considered and are found persuasive, because Arima does not teach the step of determining an area of the epidermis of the subject in which cohesion appears to be deficient due to a deficiency in synthesis of collagen VII. Thus, Examiner concluded that Arima does not teach the "subjects in need thereof" of the instant claims. Accordingly, the rejections are withdrawn. However, Applicant's arguments with respect to the 35 USC § 112, 1<sup>st</sup> paragraph rejection were not find persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 112***

Art Unit: 1617

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 70-78, 88-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Applicant's arguments with regards to this rejection have been fully considered but are not found persuasive. Applicant argues that taken as a whole the specification provides a rational for applying ellagic acid and its related compounds would improve the synthesis of Collagen VII and the cohesion between dermis and epidermis. (see Arguments at page 8, 2-4<sup>th</sup> para.). Applicant then reasons that the invention is directed to a method of improving dermis-epidermis cohesion comprising two steps; first, determining an area of the epidermis of a subject in which cohesion appears to be deficient and second, applying a composition containing ellagic acid to said area (see Arguments at page 8, 2<sup>nd</sup> para.). Applicant then concludes that the written description burden due under the 35 USC 112 1<sup>st</sup> paragraph has been met. (Id.)

5. In response, Examiner states that Applicant's statement is not clearly commensurate with the scope of the claims. The first step of the instant claim is now directed to such subjects in which cohesion appears to be deficient due to a deficiency in synthesis of collagen VII. Applicant throughout the prosecution argues such step as the trust of the invention which led to the withdrawal of the prior art rejection because the instantly recited subjects whose epidermis-dermis cohesion appears to be deficient

Art Unit: 1617

due to a deficiency in synthesis of collagen VII, are not defined or foreseen in prior art. Neither does such deficiency is an inherent feature of population who use ellagic acid compositions of the prior art. Relying on such claim limitation and reasoning, Examiner has viewed such step to be the novel concept of the instantly claimed invention and thus has withdrawn the prior art rejection.

However, the instant rejection is directed to the practice of this very step because the disclosure appears to lack sufficient written description for methods of identifying such patients in need, whose epidermis-dermis cohesion appear to be deficient due to a deficiency in synthesis of collagen VII. Subsequently, the degree of improving dermis-epidermis cohesion comprising administering ellagic acid or derivatives thereof to the subjects is also not adequately provided.

To overcome such lack of description, Applicant argues that the subjects who were envisioned to fall within the scope of the instant claims are those persons "whose skin is atonic or loose" as provided in the specification at page 3. (see Arguments at page 8, 3<sup>rd</sup> para.). In response, Examiner states that again, Applicant has not provided adequate written description as whose "atonic or loose skin" is due to a deficiency in synthesis of collagen VII and how does such epidermis area of the subject is identified or improved following administration of ellagic acid? Absent a clear identification of such population in need of the claimed therapy, one of ordinary skill in the art fails to ascertain as to what the inventor possesses at the time of filing.

In fact, there is no evidence on record or in the art showing that all patients with atonic or loose skin suffer from deficiency in synthesis of collagen VII. Therefore,

Art Unit: 1617

Examiner reiterates that it is not clear as to how applicant is in possession of the claimed invention if it is not clear who are the patients in need described in the first step? Examiner adds that if such patients are in fact any aging or elderly patients who has a loose or atonic skin, then, the prior art may be reinstated, because such characteristic of skin is an inherent function of aging skin and thus inherent to the general population.

6. Applicant also argues that specification does not require working example to satisfy the Written Description requirement (see Arguments at page 9, 1<sup>st</sup> para.). Applicant adds that specification does not require exemplifying the activity of ellagic acid in increasing the proportion of collagen VII in a culture cell and the cohesion between dermis and epidermis layer using the claimed species. (see Id. at page 9, 3<sup>rd</sup> para.).

In response, Examiner states that Applicant has a burden of clearly conveying the invention that he has in possession. Examiner viewed the inclusion of working examples as one factor in determination of what invention is applicant in possession at the time of filing? Clearly such factor is not determinative of the final conclusion, but it can aid one skilled in the art in identifying the nature of the invention which applicant may be in possession. If it is not clear what population are the recipient of the second step and how the degree of the clinical benefit is ascertained then Applicant's possession of such invention is viewed doubtful. Applicant has a burden of clearly convey such possession. Such burden has not been satisfied.

7. Applicant then argues that [the previous] Office Action actually sees to focus more on the problems with enablement (see Arguments at page 9, 1<sup>st</sup> para.). In

Art Unit: 1617

response, Examiner adds that the purpose of the "written description" requirement is broader than to merely explain how to "make and use" or simply disclose an element of a claimed invention; rather, the applicant must also convey with reasonable clarity to those skilled in the art that he or she was in possession of the invention . MPEP 2163.05 (I). Although one might not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), MPEP 2163.02.

In the instant case, the possession of the instant claimed invention as a whole is assessed based on the combined features of the claimed process steps. However, the recitation of the preamble and the first step in claim 70 was neither adequately disclosed in the specification nor described in the original claims. Thus, possession of the claimed invention at the time of filing is not clear.

8. Applicant appears to argue that the possession of the claimed invention would have been obvious in view of the knowledge available to one of ordinary skill in the art because the article by Chen et al mentioned in the first complete paragraph on page 2 of the Specification states that certain manifestation of skin aging, such as delicacy of the skin and reduced ability of the epidermis to repair itself might be attributable to a decrease in synthesis of collagen VII in elderly. (see Arguments at page 10, 1<sup>st</sup> para.).

As the initial matter, Examiner states that "the question under a [Written Description rejection] is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, the application itself must describe an

Art Unit: 1617

invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See Lockwood v. American Airlines Inc., 107 F3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997) citing Martin v. Mayer, 823 F.2d 500, 504, 3 U.S.P.Q.2D (BNA) 1333, 1337 (Fed. Cir. 1987). In fact, one must show that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. Id.

Here, the argument that one of ordinary skill in the art might have viewed the specification to render the claimed invention obvious is found persuasive, because such standard is not the applicable burden under Written Description under the 112, 1<sup>st</sup> paragraph. Rather, the standard is the ability of one skilled in the art to be able to clearly conclude that the inventor invented the claimed invention as of the filing date sought. Examiner believes that specification is void of such clear and convincing evidence.

9. Further, Applicant's reliance on Chen's teachings is replete with assumptions and uncertainties to a degree that it is not clear as to what invention is Applicant in possession of? In fact the Chen article articulates only a possibility that "the ability of epidermis to repair itself might be attributable to decrease in synthesis of collagen VII." No positive method of identifying such population who may have a decrease in synthesis of collagen VII is described in Chen.

Examiner adds that the question of whether a genus and its constituent species have been adequately described in a specification has been articulated in various court decisions. See Fujikawa v. Wattanasin, 93 F3d 1559 (Fed Cir. 1996). In one such



Art Unit: 1617

examples, a genus and its constituent species have been analogized to a forest and its trees. As the court explains in In re Ruschig:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none. In re Ruschig, 54 CCPA 1551; 379 F.2d 990, 994-995, 154 USPQ 118, 122 (1967).

Similarly, even though the use of ellagic acid has been described in the instant specification, Applicant has failed to provide specific blazemarks directing one of ordinary skill in the art to clearly identify the population in need of the instantly claimed treatment methodology and the methods of ascertaining the improvement obtained from such treatment. Accordingly, for the reasons set forth above, Examiner maintains the rejection under the 35 USC 112, 1<sup>st</sup> paragraph for lack of written description.

### ***Conclusion***

10. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

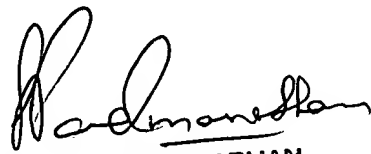
Art Unit: 1617

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**